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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,015	05/15/2002	Masayoshi Maki	56687(71526)	7186
21874	7590	06/15/2006	EXAMINER	
EDWARDS & ANGELL, LLP			FUBARA, BLESSING M	
P.O. BOX 55874				
BOSTON, MA 02205			ART UNIT	PAPER NUMBER

1618

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/030,015	MAKI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Blessing M. Fubara	1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 March 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 6,7 and 10-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6,7 and 10-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>06/21/04, 12/18/01</u> | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Examiner acknowledges receipt of request for extension of time, request for continued examination under 37 CFR 1.114, amendment and remarks, all filed 3/23/06. Claims 6,7 and 10-13 are pending.

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/23/06 has been entered.

#### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 6, 7 and 10-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Hirano et al. (US 5,820,878).

Upon further review and consideration, the indicated allowability of claims 6 and 7 is withdrawn because the consisting essentially of language in this case does not exclude the solubilizer.

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Hirano discloses a percutaneous adhesive patch (abstract; column 2, line 12; column 3, lines 54, 62 and 63) and the adhesive patch comprises softening agents such as liquid paraffin, polybutene, castor oil, cottonseed oil, palm oil, coconut oil and process oil (column 2, lines 58-6%). The patch further comprises additives such as tackifiers and the tackifiers that can be included in the patch preparation are saturated alicyclic hydrocarbon resins, rosin esters, alicyclic hydrocarbons, terpene hydrogenated resins and hydrogenated rosin esters (column 3, lines 22-2%). The patch contains at least two hormones, estrogen and luteal hormones with estradiol as the preferred estrogen and luteal hormones selected from the group consisting of progesterone, hydroxyprogesterone caproate, medroxyprogesterone acetate, dydrogesterone, chlormadinone acetate, ethisterone, dimethisterone, norethisterone, norethisterone acetate, norethisterone enanthate, ethynodiol acetate, megestrol acetate and allylestrenol (column 2, lines 14-19). Estrogen and the luteal hormones are present in amounts of 0.01 to 10% and with the luteal hormone present in about 1 to 5 times that of the estrogen (column 2, lines 20-2%). Tackifier is present in amount of 0-40% by weight of the total amount of the preparation (column 3, lines 36-45) while the softening agent is present in amounts of 10-70% by weight of the total preparation (column 3, line 13). One of the essential ingredients of the patch is a polymer base that is styrene-butadiene-styrene block copolymer or styrene-isoprene-styrene block copolymer (column 2, lines 30-43) in amounts of 20 to 90% (column 3, line 5). The composition of Hirano may further contain polyisobutylene (Example 23) and although, estradiol in Example 23 is 0.50%, Example 23 is an exemplification of one of the embodiments since Hirano discloses that estradiol in the composition is in amounts of 0.1% to 10% (column 2, lines 20 and 21).

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In example 13, the styrene-isoprene-styrene block copolymer is 27%, the liquid paraffin, which is a softener is 41% and rosin ester tackifier is 25%. In examples 15 and 16, the amount of styrene-isoprene-styrene block copolymer is 20 and 29% respectively, amount of the liquid paraffin softener is 33 and 30% respectively and the tackifier is 36 and 20% respectively. While the amount of estradiol is disclosed in column 2, lines 20-26 to be from 0.01 to 10%, Examples 13, 15, 16 disclose the amounts of estradiol to be 1%, 1% and 0.5% and these amounts are not greater than or are not more than 2%. Examples 1, 10, 12 and 14 of Hirano contain butylhydroxytoluene and the butylhydroxytoluene meets the limitation of antioxidant in claim 12. Thus Hirano meets the limitations of the claims.

**Consisting essentially of**

The transitional phrase “consisting essentially of” limits the scope of a claim to the specified materials or steps “and those that do not materially affect the basic and novel characteristic(s)” of the claimed invention. In this case, the consisting essentially of does not exclude the presence of solubilizer because the presence of a solubilizer does not affect the basic and novel characteristic of the claimed adhesive. The claimed adhesive facilitates percutaneous delivery of a drug and the “intending” is “1) a good percutaneous permeability of drug, 2) an effective use of drug in base,” (page 2, bottom half). The prior art composition had the same basic and novel characteristic (good percutaneous permeability of drug and an effective use of drug in base) and the presence of the solubilizer does not materially change the novel characteristic of the invention.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hirano et al. (US 5,820,878) in view of Hirano et al. (US 5,891,920).

Hirano ('878) is described above. Hirano discloses an adhesive composition comprising hormone, softener and solubilizer and antioxidant. The antioxidant is butylhydroxytoluene in Hirano. Hirano does not disclose the specific antioxidant recited in claim 13. It would have been obvious to substitute one antioxidant for the other and expect to have the same effect of protection from oxidation. However, Hirano ('920) discloses the use of dibutylhydroxytoluene with estradiol or norethisterone (column 5, lines 11, 12 and 56-58; column 7, lines 25 and 26). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the hormone composition of Hirano ('878) using butylhydroxytoluene as the antioxidant. One having ordinary skill in the art would have been motivated to use the dibutylhydroxytoluene according to the teaching of Hirano ('920) with the expectation of providing protection of the hormone from oxidation.

6. Claims 6, 7 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oda et al. (US 5,725,874).

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Oda discloses percutaneously absorbable preparations that comprise 20% styrene-isoprene-styrene block copolymer, polyisobutylene, liquid paraffin, rosin ester derivative, and 1% norethisterone (examples 44 and 45). The rosin ester derivative is 17% and 30% examples 44 and 45 respectively. Liquid paraffin, is 47% and 25% in examples 44 and 45 respectively. In examples 40 and 41, estradiol is the hormone active agent. Examples 40 and 41 disclose compositions containing estradiol and Example 44 discloses norethisterone containing composition and these Examples also contain polyisobutylene. 1% estradiol is not more than 2% estradiol. 3-1-menthoxy-propane-1,2-diol (abstract) is a solubilizer and claim 8 now requires the presence of a solubilizer and one solubilizer can be substituted with another. Although Oda does not disclose a composition that contains both estradiol and norethisterone, Oda discloses individual compositions that contain estradiol and norethisterone. And "it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. ...[T]he idea of combining them flows from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 198%). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the individual compositions that contain estradiol and norethisterone according to Oda. One having ordinary skill in the art would have been motivated to combine the two compositions in one composition with the expectation that the resultant composition that contains both estradiol and norethisterone would be effective for the same purpose as the individual compositions. In re Kerkhoven.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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